Exhibit 10.1

CONFIDENTIAL TREATMENT REQUESTED
WITH RESPECT TO CERTAIN PORTIONS HEREOF
DENOTED WITH "*"**

RESEARCH COLLABORATION AND LICENSE AGREEMENT

This Research Collaboration and License Agreement (the **"Agreement"**) is made as of January 20, 2009. (the **"Effective Date"**), by and between **BioDelivery Sciences International, Inc.**, a corporation having its principal place of business at 801 Corporate Center, Suite 210, Raleigh, North Carolina 27607, USA ("**BDSI**"), and **THE DRUGS FOR NEGLECTED DISEASES INITIATIVE**, a not-for-profit foundation organized under the laws of Switzerland, having its registered office at 15 chemin Louis-Dunant, 1202 Geneva, Switzerland ("**DNDi**"). BDSI and DNDi are referred to herein each individually as a "Party" and collectively as the "Parties."

RECITALS

WHEREAS, BDSI possesses proprietary technology and know-how related to the formulation of CAMB (as hereinafter defined);

WHEREAS, DNDi is developing drugs for neglected parasitic diseases such as leishmaniasis and Chagas' disease;

WHEREAS, the Parties wish to collaborate in the design and conduct of a research and clinical collaboration to assess the efficacy of CAMB in the treatment of visceral leishmaniasis and, if such efficacy is established, DNDi desires to obtain rights to register and distribute CAMB for use in the Field (as hereinafter defined) in the Territory (as hereinafter defined) on the terms and conditions hereinafter set out.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants set forth below, and for other good and valuable consideration, the receipt of which is hereby acknowledged, DNDi and BDSI hereby agree as follows:

ARTICLE 1

DEFINITIONS

1.1 References in the body of this Agreement to "Sections" will refer to the sections of this Agreement. In addition, as used herein, the following initially capitalized terms will have the following meanings:

1.2 "Affiliate" means any legal entity that directly or indirectly owns or controls or is owned or controlled by, or is under common control or ownership with, either Party, with **"control"** (for purposes of this Section 1.1) meaning the direct or indirect beneficial ownership of fifty-one percent (51%) or more of the share capital, or the power to appoint a majority of the managing directors of such legal entity.

1.3 "Agreement" means this Research Collaboration and License Agreement.

1.4 "Alliance Manager" means a single individual appointed by each Party to assist in the administration of the Agreement and to oversee the timing of events as described herein take place when and how defined.

1.5 "BDSI Background IP" means (a) any Patents or patent applications either granted or filed by BDSI and which are necessary or useful in the optimization, development, manufacturing, or distribution of CAMB and (b) any Know-How developed by or on behalf of BDSI which relates to CAMB.

1.6 "Collaboration IP" means (a) any Know-How made, developed or conceived under the R&D Plan according to this Agreement in each case solely or jointly by an employee, consultant or agent of DNDi or BDSI or their respective Affiliates, subcontractors or sublicensees, (b) any Patents describing, claiming or covering the Know-How developed according to section 1.6, a, and (c) any other intellectual property rights in or to such Know-How.

1.7 "Fully-Burdened Manufacturing Costs" means: the costs of all raw materials and labor used or consumed in such manufacture, packaging costs and expenses, shipping, handling, and delivery costs related to delivery of CAMB, quality assurances and quality control related expenses and all overhead amounts allocable to such manufacturing and delivery (including without limitation amortized capital equipment costs) provided that: (1) all of the foregoing shall be calculated in accordance with US GAAP, (ii) BDSI shall, notwithstanding anything to the contrary in the Agreement, use commercially reasonable efforts to minimize Fully-Burdened Manufacturing Costs.

1.8 "Develop" or "Development" means the performance of all pharmaceutical and pre-clinical development, clinical development activities and any post Regulatory Approval development, and regulatory activities that are required to obtain or maintain Regulatory Approval.

1.9 "Distribution" means all activities that are undertaken after obtaining Regulatory Approval to make CAMB available to prescribers and/or users in the Territory for use in the Field.

1.10 "Distribution Through the Public Sector" means Distribution, disposition or use of CAMB in the Territory for use in the Field by a Public Sector Agency.

1.11 "Governmental Authority" means any court, agency, department or other instrumentality of any foreign, federal, state, county, city or other political subdivision.

1.12 "Effective Date" means the date set forth in the first paragraph of this Agreement.

1.13 "Field" means the treatment of, African Human Trypanosomiasis (HAT), Chagas' disease and both Visceral and Cutaneous Leishmaniasis.

1.14 "Filing Party" has the meaning set out in Section 6.1.

1.15 "Joint Research Committee" or **"JRC"** has the meaning set out in Section 2.2(a).

1.16 "Know-How" means information or materials including, without limitation, discoveries (whether patentable or not), formulae, materials, practices, methods, knowledge, know-how, processes, test data (including pharmacological, toxicological and clinical information and test data), analytical and quality control data, and manufacturing, marketing, pricing, distribution, cost and sales data.

1.17 "Intellectual Property Rights" or **"IPR"** mean both Patents and Know-How.

1.18 "Laws" mean all (a) applicable laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, or other political subdivision, domestic or foreign; and (b) any guideline or directive of the World Health Organization or other applicable non-governmental agency.

1.19 "Non-Filing Party" has the meaning set out in Section 6.1.

1.20 "Patent" means any and all (a) patents and patent applications (provisional and non-provisional); (b) continuations, divisionals, continuations-in-part, continued prosecutions, re-examinations, reissues, utility models, petty and other patent applications or any applications claiming priority from any of the foregoing, and all patents that issue therefrom; (c) counterparts, substitutions, restorations, extensions (including, without limitation, patent term extensions (both administrative and regulatory and including any pediatric marketing exclusivity), supplementary protection certificates, registrations, confirmations, validations and renewals of any of the foregoing; and (d) invention certificates and other government grants for the protection of inventions or industrial designs.

1.21 "CAMB" means a pharmaceutical formulation of Amphotericin B using BDSI's encochleation technology (Bioral™ CAMB), the manufacture, use, import or distribution of which (a) incorporates BDSI Background IPR or (b) would, in the absence of a license, infringe a claim of any Patent forming part of BDSI Background IPR

1.22 "Program Data" has the meaning provided in Section 2.7(a).

1.23 "Program Manager" means the representative from DNDi responsible for managing the R&D Plan.

1.24 "Project Team" means a team composed of adequately qualified representatives of both Parties which shall be responsible for managing and guiding the research and development activities conducted under this Agreement, under the direction of the Program Manager.

1.25 "Project Plan" means a detailed plan setting forth the Parties' specific activities for one or more activities under the R&D Plan, as approved and adopted from time to time by the JRC as guided and managed by the Project Team.

1.26 "Public Sector Agency" means any Governmental Authority (but specifically excludes any military or para-military organization, branch, department or agency of any Governmental Authority) or entity organized under applicable tax laws as a non-profit or public benefit organization or entity, including, without limitation, ministries of health, governmental organizations such as the World Health Organization or UNICEF, non-governmental organizations operating for the provision of health care within the public health area such as Médecins sans Frontières or recipients of funding from the Global Fund to Fight Aids, Tuberculosis and Malaria. Public Sector Agencies specifically exclude any non-state or government-supported hospitals and clinics which wish to purchase CAMB for their own use.

1.27 "Regulatory Approval" means any and all approvals (including supplements, amendments, pre- and post-approvals), licenses, registrations or authorizations of any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, that are necessary for the manufacture, Distribution or use of CAMB in the Field in any regulatory jurisdiction within the Territory.

1.28 "Regulatory Authority" means any Governmental Authority and supranational authorities such as WHO with responsibility for granting any licenses or approvals necessary for the marketing, distribution and sale of pharmaceutical products.

1.29 "Regulatory Documentation" means, with respect to CAMB in the Field, all Regulatory Filings and supporting documents created and submitted to a Regulatory Authority, and all data contained therein, including, without limitation, any investigator's brochures, drug master files, details on the active pharmaceutical ingredient, details on the analytical methods used for the active drug substance and drug product, drug product manufacturing , process and controls, clinical and pre-clinical study reports, summary analyses, and any and all other supporting documentation, correspondence to and from a Regulatory Authority, minutes from teleconferences with Regulatory Authorities, registrations and licenses, regulatory drug lists, advertising and promotion documents shared with Regulatory Authorities, adverse event files, complaint files and manufacturing records.

1.30 "Regulatory Filing" means any and all filings required by Regulatory Authorities relating to the study, Development, manufacture or Distribution of CAMB in the Field.

1.31 "Research and Development Plan" or **"R&D Plan"** means the overall strategic plan for the evaluation of the efficacy of CAMB for use in the Field (and should efficacy be established, the strategy for all Regulatory Filing in the Territory) including all Project Plans. The R&D Plan will describe the individual objectives for pharmaceutical, preclinical and clinical development necessary for project completion and Regulatory Filing and Regulatory Approval as well as the all associated timelines and estimated budgets. The R&D Plan and the Project Plan will be conducted by DNDi and BDSI under this Agreement and as set forth in **Exhibit A** hereto, and may be amended from time to time after the Effective Date by both Parties' mutual written agreement.

1.32 "Term" has the meaning provided in Section 10.1.

1.33 "Territory" means all countries of the world excluding Japan, Australia, New Zealand, Russia, CIS countries, China, and all countries in North America and any country in, or that joins the European Union.

1.34 "Third Party" means a person or entity other than (a) DNDi, (b) BDSI, or (c) an Affiliate of either Party.

ARTICLE 2

RESEARCH AND DEVELOPMENT PROGRAM

2.1 Overview; R&D Plan. The Parties' objective is to jointly conduct the R&D Plan for the purpose of assessing the efficacy of CAMB in the Field and, if such efficacy is established, DNDi will be responsible for obtaining all Regulatory Approvals and for the Distribution Through the Public Sector of CAMB under the terms hereinafter set out. The Parties' framework for their activities hereunder is set forth in the R&D Plan, which may be amended only by mutual written agreement of the Parties. If the R&D Plan or any Project Plan conflicts with, or creates ambiguities with, this Agreement, then this Agreement will prevail.

2.2 Joint Research Committee.

(a) Formation; Composition. Promptly after the Effective Date, the Parties will appoint a joint research committee consisting of two (2) representatives from each Party (the "**Joint Research Committee**" or "**JRC**"). Either Party may change its appointed JRC members upon written notice to the other Party. The JRC will construct the R&D Plan and appoint the necessary Project Team. The JRC will oversee the activities of the Project Team including the review and approval of the Project Plan and any modifications. The JRC will continue to operate for as long as CAMB is being developed under this Agreement.

(b) Duties. The JRC will (a) oversee the conduct of the R&D Plan, (b) serve as an information-sharing forum between the Parties regarding the R&D Plan, (c) design, manage and organize clinical trials, data storage and access, (d) approve Project Plans detailing the conduct of the Project Team and the Parties' research activities, (e) review the results of the R&D Plan, including the results of on-going clinical trials, on a regular basis (to be agreed upon by the JRC), and (f) propose to the Parties modifications to the R&D Plan as appropriate. The JRC will have only those powers set forth in this Section 2.2 and will have no power to amend or waive compliance with this Agreement.

(c) Meetings. Within thirty (30) days after the Effective Date, the JRC will meet, in person or by video or teleconference to discuss and approve a Project Plan for the Parties' initial activities under this Agreement, and to finalize within 60 days of the Effective Date a complete R&D Plan to constitute the Annex A of the present Agreement. Thereafter, the JRC will meet regularly as determined by its members, in person or by video or teleconference. The JRC will be chaired by a representative of DNDi. The JRC is required to and will keep complete and accurate detailed minutes of its meetings, including any decisions made. The chair (or his or her designee) shall prepare and circulate an agenda ten (10) business days before each meeting of the JRC and meeting minutes after each meeting for review and approval by the JRC. In all cases the JRC will comply with the timings described in this section and provide the Alliance Managers with all dates and times for meetings and all minutes described in this section.

(d) Decision-Making. The JRC representatives of each Party will each have one (1) vote in the JRC. The JRC will make all decisions by majority vote and in case of deadlock the JRC shall refer the matter to the Alliance Managers who will attempt to resolve the deadlock. The Alliance Managers shall consult with each Parties executive management and attempt to resolve the dispute. For the avoidance of doubt, DNDi shall have the final decision in any matter regarding the funding of clinical trials. Should the Alliance Managers with the input of the Parties executive management be unable to resolve the dispute, the matter shall be handled as defined in Section 11.

2.3 Project Team. The JRC will establish a Project Team responsible for day-to-day management of all activities under the R&D Plan and Project Plans. The purpose of the Project Team will be to facilitate the efficient conduct of the R&D Plan, to provide information and assistance with respect to specific activities conducted under the R&D Plan, and to assist with data analysis and interpretation. It is possible that members of the Project Team could also be members of the JRC.

2.4 BDSI's Performance of the R&D Plan

(a) Research and Development Activities. BDSI agrees to use its best efforts to perform or have performed at its own cost the responsibilities assigned to it in the R&D Plan and Project Plans, all in accordance therewith and in a manner consistent with any timelines set forth therein. In particular, BDSI agrees to dedicate the appropriate number of FTEs to perform the tasks described in the R&D Plan. BDSI will ensure that its responsibilities under the R&D Plan and Project Plans are conducted in compliance with all applicable Laws or guidelines pertaining to good research practices and/or good laboratory practices.

(b) Know-How Contribution and Grant of Rights. At its own cost, BDSI will provide to DNDi all technical information and data relating to CAMB in its possession and grant DNDi all rights under BDSI Background IP which are reasonably necessary or useful for DNDi to conduct its activities under this Agreement. Determination of "reasonably necessary" shall be made in consultation with the JRC.

(c) Clinical Product Supply. BDSI will manufacture and make available to DNDi samples of CAMB in such quantities as shall be necessary for DNDi to conduct its activities under the R&D Plan. Such samples will be subject to the provisions of Section 2.6 below and sold by BDSI to DNDi at a price to be agreed between the Parties once agreement on clinical trial protocols have been reached by the JRC. DNDi and BDSI management will base the cost of clinical trial materials on the cost of the raw materials necessary for the production of CAMB and agree to a reasonable and sufficient additional cost to cover BDSI's internal costs or the costs of using an external manufacturer. DNDi acknowledges (a) any or all of BDSI's supply obligations hereunder can be supplied by Third Party subcontractors which will provide the necessary staff, equipment, instruments, raw materials and facilities to carry out BDSI's manufacturing obligations, (b) BDSI will remain responsible for the conduct of all of its obligations under this Agreement, including those conducted by such Third Party subcontractors and DNDi will have no responsibility for managing such activities or such subcontractors, (c) BDSI will keep the JRC informed of any Third Party subcontractor which BDSI engages to perform its obligations under this section of the Agreement.

2.5 DNDi's Performance of the R&D Plan.

(a) Research and Development Activities. DNDi agrees to use its best efforts to perform or have performed at its own cost the responsibilities assigned to it in the R&D Plan and Project Plans, all in accordance therewith and in the manner consistent with any timelines set forth therein. In particular, DNDi agrees to dedicate the appropriate number of FTEs to perform the tasks described in the R&D Plan. DNDi will ensure that its responsibilities under the R&D Plan and Project Plans are conducted in compliance with all applicable Laws or guidelines pertaining to good research practices and/or good laboratory practices. BDSI acknowledges and agrees that (a) DNDi's research activities under the R&D Plan can be conducted by Third Party subcontractors which will provide the research staff, equipment, instruments, supplies and facilities necessary to carry out DNDi's responsibilities under the R&D Plan and Project Plans, (b) DNDi will remain responsible for the conduct of all of its obligations under this Agreement, including those conducted by such subcontractors and BDSI will have no responsibility for managing such activities or such subcontractors, (c) DNDi will keep the JRC informed of any other Third Party subcontractor which it may subsequently engage to perform its obligations under this Agreement.

(b) Program Manager. DNDi will be responsible for the overall management of the R&D Plan through the Program Manager and the other representatives of the JRC and Project Team. DNDi, promptly after the Effective Date will appoint a Program Manager and will advise BDSI in writing of the name and qualifications of the appointed Program Manager. The Program Manager maybe removed from such appointment by a majority vote of the JRC. Should the Program Manager be removed DNDi will appoint a new Program Manager according to this section.

(c) Know-How Contribution and Grant of Rights. At its own cost, DNDi will provide to BDSI all technical information and data relating to CAMB in its possession and access to and a right of reference to all Regulatory Documentation and Regulatory Filings and grant BDSI all rights thereunder which are reasonably necessary or useful for BDSI to conduct its activities related to CAMB.

(d) Scientific Advisory Committee. BDSI acknowledges that DNDi's continued performance of the R&D Plan is subject to review by DNDi's Scientific Advisory Committee, which may recommend to terminate DNDi's performance of the R&D Plan at any time.

2.6 Material Transfer. To the extent any material is transferred by one Party to another under this Agreement the Party receiving such material will use the material solely for the purposes of performing its responsibilities assigned to it under the R&D Plan and applicable Project Plan(s) in compliance with all applicable Laws. Neither Party will use the other Party's material for any other purposes. Neither Party will sell, transfer, disclose or otherwise provide access to the other Party's material without the prior written consent of the other Party; *provided* that each Party may allow access to the other Party's material to such first Party's employees, consultants, agents and subcontractors for purposes of performing the R&D Plan in accordance with the applicable Project Plan(s), and *provided further* that such employees, agents and subcontractors are apprised of the proprietary nature of such material and are bound by written agreement to protect the confidentiality of such material and any results obtained from working with such material and to assign to the subcontracting Party any IPR made in the course of working with such material. Upon completion of all activities under the R&D Plan or the earlier expiration or termination of this Agreement, each Party will return any remaining quantities of the other Party's material to such other Party, or otherwise dispose of such material as directed by such other Party and certify in writing to the other Party such destruction has taken place.

2.7 Data and Reports.

(a) Data. Each Party will keep complete and accurate notes, accounts and records of the data, results, materials, or other information arising out of or resulting from the research performed by such Party under this Agreement (collectively, "**Program Data**"). The Program Data will be deemed the Confidential Information of both Parties under this Agreement, and both Parties shall have unfettered rights to access and reference to the Program Data in support of their clinical and regulatory activities.

(b) Reports. For so long as a Party has obligations to conduct research or development activities under the R&D Plan, such Party will provide written quarterly reports to the JRC, and additional updates as requested by the JRC, summarizing all Program Data created in the preceding quarter by such Party, including a description of any inventions made, developed, conceived or reduced to practice by such Party. The purpose of these reports is to ensure the continuous sharing between the Parties of information regarding results achieved under the R&D Plan and to enable any Party to take prompt action to file any patent applications covering the Collaboration IP. In addition, each Party will submit to the JRC semi-annual written reports outlining the milestones achieved by such Party, key decisions made, and progress toward achieving the objectives set forth in the R&D Plan. The JRC will provide to the Alliance Managers copies of all reports required under this section and it will be the responsibility of the Alliance Managers to assure the JRC and their respective Party complies with all responsibilities under this section in a timely manner.

ARTICLE 3

REGULATORY APPROVALS, MANUFACTURE AND DISTRIBUTION

3.1 Allocation of Responsibilities. Beginning with the completion of the R&D Plan, DNDi will have sole responsibility for seeking and obtaining Regulatory Approvals for CAMB, and for the Distribution Through the Public Sector of CAMB in the Territory for use in the Field. DNDi may use a third party for Regulatory Approval activities, provided that the terms of the agreements with such third party conform to the terms of the present Agreement. BDSI shall have sole responsibility for the manufacture and supply to DNDi of CAMB for DNDi's Distribution.

3.2 Regulatory Approvals. DNDi will be responsible, either directly or through a third party, and shall bear all costs for developing Regulatory Documentation, preparing and submitting Regulatory Filings, and seeking and maintaining Regulatory Approvals in the Territory for CAMB's use in the Field. BDSI agrees to provide DNDi with all information and data in its possession relating to CAMB and to cooperate with DNDi, as reasonably requested by DNDi, in preparing and filing all Regulatory Documentation. DNDi will have the right to use all parts of the Program Data for developing Regulatory Documentation and BDSI will have the right to access or reference any of DNDi's Regulatory Approvals for BDSI's private sector Distribution of CAMB in or outside the Territory. Prior to DNDi providing a Regulatory Authority any Regulatory Documents in conjunction with any Regulatory Filing, DNDi will engage BDSI for review and comment on the Regulatory Documents prior to submission.

3.3 Manufacture and Supply. During the Term and subject to the provisions of Section 4.1, BDSI will be responsible for the exclusive, subject to section 3.3 (a), manufacture and supply of CAMB to DNDi for Distribution in the Territory and for all costs associated therewith. Prices at which BDSI will sell CAMB to DNDi are set out in section 5.3 below.

(a) Should BDSI be unable to meet DNDi's Distribution needs as evidenced by failure to meet *** of DNDi's forecast needs for *** consecutive quarters, DNDi shall be able to engage a secondary supplier to meet any BDSI shortfall in DNDi's supply needs with the assistance of BDSI. However, in every instance, DNDi shall purchase the full quantity of CAMB available from BDSI prior to engaging a secondary manufacturer. Should DNDi engage a secondary supplier due to BDSI shortfall of DNDi's Distribution needs, DNDi will revert back to BDSI as the exclusive supplier of DNDi's needs once BDSI is able to show manufacturing capacity equivalent to *** of DNDi's forecast needs for any upcoming quarter.

(b) Should BDSI determine, in its sole discretion, that parallel importing, or diversion by or through any mechanism, that Distribution Through the Public Sector is adversely impacting the sales of CAMB sold by BDSI, the parties will meet, discuss and DNDi will assist BDSI in developing and implementing mechanisms to stop any parallel importing, diversion or other mechanism adversely impacting BDSI's sales of CAMB.

3.4 Adverse Event Reporting. DNDi will maintain a record of all non-medical and medical complaints and reports of adverse events which it shall receive with respect to the use of CAMB. DNDi will be responsible for reporting to Regulatory Authorities any such adverse events in compliance with all applicable Laws in each country of the Territory, and will promptly thereafter provide copies of all adverse events reports to BDSI.

3.5 Regulatory Approvals and Distribution Diligence; Progress Reports. DNDi will use diligent efforts for seeking Regulatory Approvals and for initiating and developing Distribution Through the Public Sector in the Territory for use in the Field during the Term. Once all activities under the R&D Plan are completed, DNDi will provide annual written progress reports to BDSI summarizing the status of Development and Distribution of CAMB during the prior year. DNDi will provide such progress report

to BDSI no later than each anniversary of the Effective Date following the completion of all activities under the R&D Plan. The Parties shall additionally regularly discuss Distribution progress through the Parties respective Alliance Managers.

ARTICLE 4

LICENSES

4.1 Licenses to DNDi. Subject to all of the terms and conditions of this Agreement, BDSI hereby grants DNDi:

(a) a worldwide, non-exclusive, royalty-free and fully paid-in, sublicensable (as permitted under Section 4.3) license to use BDSI Background IP for the purpose of conducting DNDi's activities under the R&D Plan;

(b) an non-exclusive, royalty-free, irrevocable and fully paid-in, sublicensable (as permitted under Section 4.3) license to use BDSI Background IP and Collaboration IPR for the purpose of seeking Regulatory Approvals and undertaking Distribution Through the Public Sector in the Territory for use in the Field; *provided, however* that if, for any reason, BDSI is unable to supply CAMB ordered by DNDi or its nominee for Distribution Through the Public Sector, for use in the Field, in the Territory, this exclusive license shall be automatically extended to include the right for DNDi to manufacture CAMB, or to have CAMB manufactured by any Third Party, for the sole purpose of its Distribution Through the Public Sector in the Territory for use in the Field, subject to section 3.3.

4.2 License to BDSI. Subject to the terms and conditions of this Agreement, DNDi hereby grants BDSI a worldwide, exclusive, royalty-free, irrevocable and fully paid-in, sublicensable, license to make, have made, use, have used, offer to sell, sell, have sold, or import or have imported CAMB under the Collaboration IP (as defined under Section 6.1).

4.3 Sublicensing. DNDi may grant sublicenses to its Affiliates or to Third Parties under the licenses granted in Section 4.1 with the prior written consent of BDSI, not to be unreasonably withheld, provided that each approved sublicensee agrees to be bound by the terms of this Agreement.

4.4 No Implied Rights or Licenses; Retained Rights. Neither Party grants to the other Party any rights or licenses, including without limitation to any Patent, Know-How, or other intellectual property rights, by implication, estoppel or otherwise, except to the extent expressly provided in this Agreement. BDSI retains all rights in the BDSI Background IP and Collaboration IP that are not granted to DNDi in Section 4.1 or 6.1, including all rights to manufacture, sell and Distribute CAMB in the Territory in any manner and context that is not Distribution Through the Public Sector.

4.5 Limitation to Territory. DNDi and its Affiliates, sublicensees, and distributors shall not Distribute CAMB outside the Territory or for use outside the Field, or conduct any Distribution except for Distribution Through the Public Sector. DNDi and its Affiliates, sublicensees, and distributors shall refer to BDSI any inquiries or orders for CAMB that they receive, where DNDi believes the use will be outside of the Field, or from outside the Territory or from any Third Party other than Public Sector Agencies. DNDi shall additionally take all reasonable steps ((as further described in section 3.3 (b), and such as by example, but not limitation, changes in packaging and trade dress, use of tamper resistant materials and the like), necessary and work with and assist BDSI in preventing the redistribution, parallel importation or diversion of DNDi's supply of CAMB.

ARTICLE 5

FINANCIAL TERMS

5.1 No Payment or Financial Contribution. Except as specifically set out in this Agreement, neither Party shall make any payment or pay any financial contribution to the other Party and each Party will bear all expenses it will incur for the performance of its own obligations under or in connection with this Agreement.

5.2 Funding of Clinical trials; Fees and Duties. DNDi will be solely responsible and pay for (a) all costs related to the clinical trials to be conducted upon CAMB to assess its efficacy in the Field as part of the R&D Plan and (b) all taxes, fees, duties and payments to any Governmental Authority in connection with the Regulatory Approvals and the Distribution Through the Public Sector in the Territory.

5.3 Product Supply. BDSI will, other than the clinical trial supplies as discussed in section 2.4, supply CAMB to DNDi at the following prices: Fully-Burdened Manufacturing Cost increased by a margin not exceeding *** for all supplies of CAMB for use in the Field and Distribution Through the Public Sector in the Territory. Once BDSI receives a first approval for CAMB, BDSI shall supply CAMB to DNDi at BDSI's Fully-Burdened Manufacturing Costs increased by a margin not exceeding *** for all supplies of CAMB for use in the Field and Distribution Through the Public Sector in the Territory. BDSI and DNDi agree that the cost for lot failures, batch failures, or other quality control or productions failures (collectively "failures") will be shared equally between the parties and BDSI shall keep all the necessary records to document failures and allocate costs accordingly.

ARTICLE 6

INTELLECTUAL PROPERTY

6.1 Ownership of Collaboration IP. (a) All Collaboration IP which is made, developed or conceived jointly by employees, consultants or agents of both Parties or their respective Affiliates, subcontractors or sublicensees will be jointly owned by both Parties and if any part of such Collaboration IP is patentable, both Parties, through the Alliance Managers, shall select by mutual agreement in writing the Party which will file and prosecute the relevant Patents, in its own name and at its own cost ("the Filing Party") and the other Party ("the Non-Filing Party") will assign to the Filing Party all its rights, title and interest in and to the Collaboration IP and will agree to provide the Filing Party with all consents and assistance as may be reasonably requested by the Filing Party to perfect its rights in the relevant Patents in return for the Filing Party granting the other Party a license according to section 4. (b) All Collaboration IP which is made, developed or conceived solely by employees, consultants or agents of either Party or its Affiliates, subcontractors or sublicensees shall be solely owned by such Party ("DNDi Collaboration IPR" or "BDSI Collaboration IPR"), and if any part is patentable, such Party shall be solely entitled to file and prosecute any relevant Patent, in its own name and at its own cost, provided that the non-Filing Party will be automatically granted a license to such Collaboration IP according to section 4.

6.2 Disclosure of Inventions. On a quarterly basis in accordance with Section 2.7 (b), each Party will disclose in writing to the JRC all Know-How and inventions made, developed, conceived or reduced to practice, either in the course of or arising directly out of the performance of such Party's obligations under the R&D Plan, or any activities under this Agreement, by or on behalf of such Party or its employees, consultants, Affiliates, agents, subcontractors or sublicensees. Each Party will ensure that each of its Affiliates' employees, agents, consultants and subcontractors conducting activities under the R&D Plan has a contractual obligation to disclose all such inventions and, to assign all intellectual property rights developed thereunder.

6.3 Prosecution and Maintenance of Patents. Subject to the provisions of Section 4 and 6.1, the Filing Party will have the sole right and authority to prepare, file, prosecute, and maintain any Patent in the Collaboration IP defined in Section 6.1 throughout the world at its own expense. The Non-Filing Party will provide the Filing Party at its own request with all reasonable assistance and cooperation, including providing any necessary powers of attorney and executing any other required documents or instruments. If the Filing Party determines in its sole discretion to abandon or not maintain any Patent in the Territory, it shall promptly provide the Non-Filing Party with reasonable prior written notice of such determination, which shall in any event not be less than thirty (30) days prior to any abandonment or pending action date, along with copies of all material filings and correspondence with the applicable patent offices and any other relevant information regarding pending deadlines. The Non-Filing Party shall then have the right, at its expense, to assume responsibility for prosecuting and maintaining such Patent, provided that it shall not file any patent application claiming priority to such Patent without the prior written consent of the Filing Party, which in their sole discretion they may approve or deny for any reason. If the Non-Filing Party decides to assume such responsibilities, it shall so inform the Filing Party in writing, and the Filing Party shall use commercially reasonable efforts to cooperate with the Non-Filing Party to transfer such responsibilities to the Non-Filing Party and assign such Patent to the Non-Filing Party, at the Non-Filing Party's expense.

6.4 Enforcement of Patents. (a) DNDi will promptly notify BDSI in writing upon learning of any alleged or threatened infringement of any Patent forming part of BDSI Background IP or BDSI owned Collaboration IP and BDSI will have the sole right to bring an appropriate suit or other action against any person or entity engaged in such alleged or threatened infringement, at its own expense. DNDi will provide all reasonable assistance to BDSI in such enforcement, including, without limitation, furnishing a power of attorney or joining such action as a necessary party, at BDSI's reasonable expense. BDSI will retain any and all recoveries realized as a result of such litigation. (b) Either Party will promptly notify the other Party in writing upon learning of any alleged or threatened infringement of any Patent forming part of the jointly owned Collaboration IP defined in Section 6.1 and the Parties, through the Alliance Managers, will decide which Party or whether both Parties shall bring an appropriate suit or other action against any person or entity engaged in such alleged or threatened infringement, and how any such action will be funded. The other Party will provide all reasonable assistance in such enforcement, including, without limitation, furnishing a power of attorney or joining such action as a necessary party, at the other Party's reasonable expense. The Party bringing suit and funding the action will retain any and all recoveries realized as a result of such litigation.

6.5 Defense of Third Party Infringement Claims. If the manufacture, use, Distribution, or importation of CAMB pursuant to this Agreement results in any claim, suit, or proceeding by a Third Party alleging that such activities infringe a Third Party Patent, or if a Third Party threatens such a claim, suit or proceeding, the Party first having notice of the claim will promptly notify the other Party thereof, and the Parties, through their respective Alliance Managers, will promptly consult to discuss the claim and to agree in writing upon the actions to be taken to defend or settle such claim, the cost allocation for the defense or settlement, and the responsibilities of each Party in relation thereto. Neither Party shall enter into any settlement that affects the other Party's rights or interests without first obtaining such other Party's written consent, not to be unreasonably withheld or delayed.

6.6 Patent and Trademark Marking. Each Party shall mark, if necessary and requested by a Party, all materials manufactured, supplied or used under the terms of this Agreement, or their containers, in accordance with the applicable Patent and Trademark marking Laws in conjunction with and at the direction of the Party holding any patents or trademarks covering CAMB.

ARTICLE 7

CONFIDENTIALITY

7.1 Treatment of Confidential Information. Any and all information disclosed or submitted in writing or in other tangible form under this Agreement or the R&D Plan to one Party by the other Party during the Term will hereinafter be referred to as the **"Confidential Information"** of the disclosing Party. In addition, all confidential information disclosed under the Confidentiality Agreement between the Parties, dated March 12, 2008, between DNDi and BDSI (the **"Confidentiality Agreement"**) shall be deemed Confidential Information under this Agreement, and the Confidentiality Agreement is hereby terminated and shall be of no further force and effect. Each Party will receive and maintain the other Party's Confidential Information in strict confidence and in accordance with all applicable laws, rules and regulations. Each party also agrees not to use the Confidential Information disclosed to it by the other Party for its own, independent use or in any way, directly or indirectly, harmful or competitive with the other Party. Each Party acknowledges that the confidentiality provisions of this Agreement shall be deemed to be an agreement to keep each Party's Confidential Information in confidence as contemplated by Regulation FD promulgated by the United States Securities and Exchange Commission. In addition, DNDi acknowledges and agrees that some BDSI Confidential Information maybe considered "material non-public information" for purposes of the United States' securities laws and that DNDi and its officers, directors, employees and agents will abide by all such laws relating to the handling of and acting upon such Confidential Information. Except as provided under this Section 7.1, neither Party will disclose any Confidential Information of the other Party to any Third Party. Neither Party will use the Confidential Information of the other Party for any purpose other than as required to perform that Party's obligations, or exercise that Party's rights hereunder. Each Party may disclose the other Party's Confidential Information to the receiving Party's Affiliates, employees, consultants or agents requiring access thereto for the purposes of this Agreement, *provided, however*, that prior to making any such disclosures, each such Affiliate, employee, consultant or agent will be bound by written agreement to maintain Confidential Information in confidence and not to use such information for any purpose other than in accordance with the terms and conditions of this Agreement. Each Party agrees to take all reasonable steps necessary to ensure that the other Party's Confidential Information will be maintained in confidence, including (without limitation) such steps as it takes to prevent the disclosure of its own proprietary and confidential information of like character. Each Party agrees that this Agreement will be binding upon its Affiliates, and upon the employees, consultants and agents involved under this Agreement and in conjunction with the R&D Plan of such Party and its Affiliates. Each Party will take all steps necessary to ensure that its Affiliates, employees, consultants and agents will comply with the terms and conditions of this Agreement. The foregoing obligations of confidentiality and non-use will survive, and remain in effect for a period of five (5) years from, the termination or expiration of this Agreement.

7.2 Exclusions from Nondisclosure Obligation. The nondisclosure and nonuse obligations in Section 7.1 will not apply to any specific portion of Confidential Information to the extent that the receiving Party can establish by competent written proof that:

(a) it is or was in the public domain at the time of its disclosure; or

(b) after disclosure, it becomes part of the public domain by publication or otherwise, except by breach of its obligations under section 7.1 by the receiving Party; or

(c) it was in such receiving Party's possession at the time of its disclosure; or

(d) it is received by such receiving Party on a non-confidential basis from a Third Party who has the lawful right to disclose such information; or

(e) it is independently discovered or developed by the receiving Party or its Affiliate without the aid, application, or use of Confidential Information of the other Party.

7.3 Permitted Disclosures. Each Party may disclose Confidential Information of the other Party to the extent such disclosure is reasonably necessary in the following situations:

(a) filing or prosecuting Patents forming part of the Collaboration IP;

(b) regulatory filings with any Governmental Authority or stock exchange;

(c) prosecuting or defending litigation; or

(d) complying with applicable Laws or the valid and enforceable order of a court of competent jurisdiction.

In each case, in section 7.3, the Party obligated or making such disclosure will (i) give at least a sixty (60) day advance written notice to the other Party, (ii) make a reasonable effort to obtain confidential treatment of the Confidential Information so disclosed, and (iii) disclose the Confidential information only to the extent reasonably necessary or required.

7.4 Return of Confidential Information. Promptly after the termination or expiration of this Agreement for any reason, each Party will return to the other Party, or destroy as directed by such other Party, all tangible manifestations of such other Party's Confidential Information, and delete all electronic manifestations of such other Party's Confidential Information, at that time in the possession of the receiving Party and certify to the other Party that all information has been returned, destroyed or deleted.

7.5 Publication. DND*i* supports the timely communication of its collaborative research, and will facilitate the rapid and accurate communication of DND*i*-collaborative research and clinical trial results to the wider scientific and medical communities in the most appropriate and practicable way. Thus, each Party recognizes to the other Party the right to jointly communicate and/or publish the results generated through the activities of the Research and Development Plan. The Parties acknowledge that each Party's researchers engaged in the Research and Development Plan shall be permitted to present at symposia, national, or regional professional meetings, and to publish in journals, theses or dissertations, or otherwise of their own choosing, selected results obtained during the performance of the Research and Development Plan, provided, however, that the publishing Party shall submit copies to the other Party of any proposed publication or presentation in advance of such proposed publication or presentation to a journal, editor, or other third party. The other Party shall have thirty (30) days, after receipt of said copies, to object or to amend such proposed presentation or publication on the grounds of the existence of a patentable subject matter for which it will seek protection. In the event that the other Party makes such determination, the publishing Party shall refrain from making such publication or presentation for a maximum of ninety (90) days from date of receipt of such determination in order to allow the other Party to file patent application(s) with the appropriate patent office(s) upon the patentable subject matter contained in the proposed publication or presentation.

ARTICLE 8

REPRESENTATIONS AND WARRANTIES

8.1 Mutual Representations and Warranties. Each of BDSI and DNDi hereby represents, warrants and covenants to the other as of the Effective Date that:

(a) it has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof, and this Agreement is legally binding upon it and enforceable in accordance with its terms;

(b) the execution, delivery and performance of this Agreement by it does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any Law of any Governmental Authority having jurisdiction over it;

(c) it has (or will have at the time performance is due) maintained and will maintain and keep in full force and effect all agreements necessary to perform its obligations hereunder;

(d) all necessary consents, approvals and authorizations of all Governmental Authorities and other persons required to be obtained by such Party to enter into, or perform its obligations under, this Agreement have been (or will have been at the time performance is due) obtained; and

(e) in the course of conducting its activities under the R&D Plan, it will not use any employee, agent, or contractor who has been debarred by any Regulatory Authority or, to the best of its knowledge, is the subject of debarment proceedings by a Regulatory Authority.

8.2 BDSI Representations and Warranties. BDSI hereby represents, warrants and covenants to DNDi, as of the Effective Date, that:

(a) it is the rightful owner of, or has to the best of its knowledge the lawful right to use, BDSI Background IPR in the Field and in the Territory for CAMB;

(b) it has all rights and authority to authorize or license DNDi to use BDSI Background IPR in the Field for CAMB under the terms hereunder;

(c) it has not granted to any of its Affiliates or any Third Party any, license or interest in, to or under BDSI Background IPR which may prevent, restrict or limit in any respect DNDI's ability to use BDSI Background IPR for CAMB hereunder;

(d) to the best of its knowledge, there is no action, suit, investigation, claim, proceeding pending or threatened relating to BDSI Background IPR;

(e) during the Term, it will not grant to any of its Affiliates or any Third Party any right, license or interest in, to or under BDSI Background IPR for CAMB which would be inconsistent with any of the rights, licenses and interests granted to DNDI hereunder.

ARTICLE 9

INDEMNIFICATION

9.1 Indemnification by DNDi. DNDi will indemnify, defend and hold harmless BDSI, its Affiliates, and their respective officers, directors, employees and agents (the **"BDSI Indemnitees"**) from and

against any and all liability, loss, damage or expense (including without limitation reasonable attorneys' fees) suffered as a result of any Third Party claims, demands and actions (collectively, "**Losses**"), to the extent such Losses result from (a) a breach by DNDi of any of its representations, warranties or covenants in this Agreement or (b) the gross negligence or willful misconduct by DNDi or its Affiliates or their officers, directors, employees or agents. The foregoing indemnity obligation will not apply to the extent any Loss arises from (i) a breach by BDSI of its representations, warranties or covenants in this Agreement or (ii) the gross negligence or willful misconduct of any BDSI Indemnitee.

9.2 Indemnification by BDSI. BDSI will indemnify, defend and hold harmless DNDi, its Affiliates, and their respective officers, directors, employees and agents (the **"DNDi Indemnitees"**) from and against any and all liability, loss, damage or expense (including without limitation reasonable attorneys' fees) suffered as a result of any Third Party claims, demands and actions (collectively, "**Losses**"), to the extent such Losses result from (a) a breach by BDSI of any representation, warranty or covenant in this Agreement, (b) the gross negligence or willful misconduct by any BDSI Indemnitee or (c) a manufacturing defect in the production of CAMB, including, without limitation, Losses related to the death of or injury to a Third Party caused by CAMB, if the applicable Loss stemmed from CAMB defectively manufactured by BDSI. The foregoing indemnity obligation will not apply to the extent any Loss arises from (i) a breach by DNDi of its representations, warranties or covenants in this Agreement or (ii) the gross negligence or willful misconduct of any DNDi Indemnitee.

9.3 Procedures. The indemnification obligations in Sections 9.1 and 9.2 are conditioned on the indemnified Party (a) providing prompt written notice to the other Party of any claim giving rise to an indemnification obligation hereunder, (b) permitting the indemnifying Party to assume full responsibility to investigate, prepare for and defend against any such claim, (c) providing reasonable assistance in the defense of such claim at the indemnifying Party's reasonable expense, and (d) not compromising or settling such claim without the indemnifying Party's advance written consent.

9.4 Insurance. Each Party will maintain comprehensive general liability insurance coverage, including products liability coverage, in reasonable amounts that are appropriate with respect to its obligations and liabilities under this Agreement and will provide the other Party, if requested, with copies of its relevant insurance policies and evidence of payment of all insurance premiums due.

9.6 Limitation of Liability. NEITHER PARTY NOR ITS RESPECTIVE AFFILIATES WILL BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, EXEMPLARY, CONSEQUENTIAL OR PUNITIVE DAMAGES UNDER THIS AGREEMENT, WHETHER IN CONTRACT, WARRANTY, TORT, STRICT LIABILITY OR OTHERWISE.

ARTICLE 10

TERM

10.1 Term. Unless terminated earlier under this Article 10, the term of this Agreement will commence on the Effective Date and will continue until the expiry of the last-to-expire United States Patent forming part of the Collaboration IP or BDSI Background IP, or the expiration of any data exclusivity period in the United States, whichever is later. (the "**Term**")

10.2 Termination by DNDi. DNDi may terminate this Agreement at any time during the R&D Plan, as set out in Section 2.5 (c), upon thirty (30) days written notice to BDSI.

10.3 Termination for Breach. Either Party may terminate this Agreement in its entirety upon the uncured material breach of this Agreement by the other Party in accordance with this Section 10.3, in which case the non-breaching Party will deliver notice of such material breach to the breaching Party describing in detail the nature of the breach. The breaching Party will have forty-five (45) days from receipt of such notice to cure the breach. Any such termination will become effective at the end of the 45-day period unless the breaching Party has cured any such breach or default prior to the expiration of the 45-day period (or, if such default is capable of being cured but cannot be cured within such 45-day period, the breaching Party has commenced and diligently continued actions to cure such default, in which case the non-breaching Party may not terminate this Agreement).

10.4 Consequences of Termination. Termination of this Agreement will be without prejudice to or limitation on any other remedies or any accrued obligations of either Party. In addition, Section 4, 10.4 and Articles 6, 7, 8, 9 and 11 will survive any termination or expiration of this Agreement.

ARTICLE 11

MISCELLANEOUS

11.1 Dispute Resolution. Unless otherwise set forth in this Agreement, in the event of a dispute arising under this Agreement between the Parties, either Party shall have the right to refer such dispute to their Alliance Managers, respective chief executive officers, their designees (or equivalent), and such officers shall attempt in good faith to resolve the dispute. If the Parties are unable to resolve a given dispute pursuant to this Section 11.1 within sixty (60) calendar days of referring such dispute to the chief executive officers, their designees (or equivalent), either Party may have the dispute settled by binding arbitration pursuant to Section 11.2.

11.2 Arbitration. If a Party intends to initiate arbitration to resolve a dispute arising under this Agreement, such Party shall provide written notice (the **"Arbitration Request"**) to the other Party of its intention and the issues for resolution. From the date of the Arbitration Request until such time as the dispute has become finally settled, the running of the time periods as to which a Party must cure a breach of this Agreement becomes suspended as to any breach that is the subject matter of the dispute.

(a) Arbitration of Patent/Confidentiality Issues. Unless otherwise agreed by the Parties, disputes arising between the Parties relating to Patents and non-disclosure, non-use and maintenance of Confidential Information shall be settled by arbitration under the Rules of Arbitration of the World Intellectual Property Organization by three (3) arbitrators appointed and acting in accordance with such Rules. Arbitration proceedings shall be conducted in the English language in Geneva, Switzerland.

(b) Arbitration Procedure. All disputes arising between the Parties other than those defined in paragraph (a) above will be finally settled by arbitration under the Rules of the International Chamber of Commerce by three (3) arbitrators appointed and acting in accordance with such Rules. Arbitration proceedings shall be conducted in the English language in Paris, France.

(c) Fees. Each Party shall bear its own attorneys' fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators.

11.3 Governing Law. This Agreement and any dispute arising from the performance or breach hereof shall be governed by and construed and enforced in accordance with the laws of England without reference to conflicts of laws principles

11.4 Export Clause. The Parties acknowledge that the laws and regulations of the countries of the Territory may restrict the import and export of pharmaceutical products and technical data. Each Party agrees that it will not import or export CAMB under this Agreement to or from any country in the Territory without having first obtained the appropriate licenses, permits, and safety clearances.

11.5 Independent Contractors. The Parties will perform their obligations under this Agreement as independent contractors, and nothing in this Agreement will be construed to be inconsistent with such relationship or status. This Agreement will not constitute, create or in any way be interpreted as a joint venture or partnership of any kind.

11.6 Notices. Any notice or request required or permitted to be given under or in connection with this Agreement shall be deemed to have been sufficiently given if in writing and personally delivered or sent by certified mail (return receipt requested), facsimile transmission (receipt verified), or overnight express courier service (signature required), prepaid, to the Party for which such notice is intended, at the address set forth for such Party below:

If to BDSI, addressed to:	BioDelivery Sciences International, Inc. 801 Corporate Center, Suite 210 Raleigh, North Carolina 27607, USA Attention: General Counsel Facsimile: 919-582-9051
If to DNDi, addressed to:	Drugs for Neglected Diseases Initiative (DNDi) 15 chemin Louis Dunant 1202 Geneva Switzerland Attention: Business Development Director Facsimile: +41 (22) 906 9231

or to such other address for such Party as it shall have specified by like notice to the other Party, provided that notices of a change of address shall be effective only upon receipt thereof. If delivered personally or by facsimile transmission, the date of delivery shall be deemed to be the date on which such notice or request was given. If sent by overnight express courier service, the date of delivery shall be deemed to be the next business day after such notice or request was deposited with such service. If sent by certified mail, the date of delivery shall be deemed to be the third business day after such notice or request was deposited with the postal service.

11.7 Assignment. Neither Party may assign in whole or in part this Agreement without the advance written consent of the other Party, except that BDSI may assign this Agreement in its entirety to its successor-in-interest in connection with a merger, consolidation, or other corporate reorganization, or the sale of all or substantially all of its assets to which this Agreement relates. Any assignment or purported assignment in violation of this Section 11.7 will be null and void.

11.8 Force Majeure. Both Parties will be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse will be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, force majeure will include conditions beyond the reasonable control of the Parties, including, without limitation, an act of God, voluntary or involuntary compliance with any regulation, Law or order of any government, war, civil commotion, labor strike or lock-out, acts of terrorism, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe.

11.9 Headings. The headings for each article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular article or section.

11.10 English Language. All notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement will be in the English language. This Agreement is in the English language only, which language will be controlling in all respects, and all versions and translations hereof in any other language will be for accommodation only and will not be binding upon the Parties.

11.11 No Waiver. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter will not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, excepting only as to an express written and signed waiver as to a particular matter for a particular period of time.

11.12 Entire Agreement. This Agreement (including its Exhibits) sets forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties with respect to the subject matter hereof and supersedes and terminates all prior agreements and understanding between the Parties with respect to such subject matter. No subsequent alteration, amendment, change or addition to this Agreement will be binding upon the Parties unless reduced to writing and signed by the respective authorized officers of the Parties.

11.13 Severability. If one or more of the provisions in this Agreement are deemed unenforceable by Law, then such provision will be deemed stricken from this Agreement and the remaining provisions will continue in full force and effect.

11.14 Counterparts. This Agreement may be executed in one or more identical counterparts, each of which will be deemed to be an original, and which collectively will be deemed to be one and the same instrument.

11.15 Publicity. DNDi and BDSI shall consult with each other before issuing any press release or public statement with respect to this Agreement or the provisions contemplated herein and neither shall issue any such press release or make any such public statement without the prior consent of the other, which consent shall not be unreasonably withheld; provided, however, (a) that a Party may, without the prior consent of the other Party, issue such press release or make such public statement as may, upon the advice of counsel, be required by law or the rules and regulations of any stock exchange, or (b) if it has made reasonable attempts and

has used reasonable efforts to consult with the other Party prior thereto, such consent shall be deemed to have been given if the recipient of the press release or public statement fails to respond to the other Party within two business days after the recipient's receipt of such press release or public statement. Notwithstanding the foregoing, each Party agrees to use its best efforts to review and comment on the other Party's suggested press release or public statement within two business days and agrees to continue such review in serial fashion until agreement as been reached on the final form of all press releases or public statements. No such consent of the other Party shall be required to release information which has previously been made public.

[*Signature page to follow.*]

IN WITNESS WHEREOF, the Parties have by duly authorized persons executed this Agreement as of the Effective Date.

THE DRUGS FOR NEGLECTED DISEASES INITIATIVE

By: /s/ Bernard Pécoul
Name: Bernard Pécoul
Title: Executive Director

Date: January 20, 2009

By: /s/ Jean-Pierre Paccaud
Name: Jean-Pierre Paccaud
Title: Business Development Director

Date: January 20, 2009

BIODELIVERY SCIENCES. INTERNATIONAL INC.

By: /s/ Mark A. Sirgo
Name: Mark A. Sirgo
Title: President and CEO

Date: January 20, 2009

EXHIBIT A

RESEARCH AND DEVELOPMENT PLAN

<to be completed>

BDSI/DNDi understood Research and Development Program Progression

1) **Parties appoint the JRC**
2) **JRC develops the R&D Plan**
3) **JRC appoints the Project Team**
4) **JRC reviews and approves the Project Plan(s)**
5) **JRC reviews the results of the Project Team's activities**
6) **JRC recommends to the Parties modifications of the R&D Plan as necessary**
7) **JRC reviews and approves modifications to the Project Plans**
8) **Alliance Managers are responsible for JRC complying with Agreement based time tables.**